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Primary Angioplasty in Acute Myocardial Infarction at Hospitals With No Surgery On-Site (The PAMI-No SOS Study) Versus Transfer to Surgical Centers for Primary Angioplasty

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OBJECTIVES To investigate primary angioplasty (PA) for high-risk acute myocardial infarction (AMI) at hospitals with no cardiac surgery on-site (No SOS), we hypothesized that a nonrandomized registry of such patients treated with PA would show clinical outcomes similar to those of a group randomized to transfer for PA, and that reperfusion would occur faster.

BACKGROUND Primary angioplasty provides outcomes superior to fibrinolytic therapy in AMI, but its use in community hospitals with No SOS has been limited.

METHODS Fibrinolytic-eligible patients with high-risk AMI prospectively consented if they had one or more high-risk characteristic. Nineteen hospitals with No SOS prospectively enrolled 500 patients for PA on-site. Seventy-one similar Air Primary Angioplasty in Myocardial Infarction trial patients were randomized to transfer for PA.

RESULTS Primary angioplasty was performed in 88% of patients. Patients transferred for PA had a longer mean time to treatment (187 vs. 120 min; $p < 0.0001$). Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 was achieved in 96% for on-site PA, 86% in the transfer group ($p = 0.004$). The combined primary end point of 30-day mortality, re-infarction, and disabling stroke occurred in 27 (5%) on-site PA patients and 6 (8.5%) transfer patients ($p = 0.27$). Unadjusted one-year mortality was improved in on-site PA patients compared with those transferred (6% vs. 13%, $p = 0.043$), but after adjustment for differences in baseline variables, this difference was not significant.

CONCLUSIONS On-site PA and transfer groups had similar 30-day outcomes and more rapid reperfusion for on-site PA. Primary angioplasty in high-risk AMI patients at hospitals with No SOS is safe, effective, and faster than PA after transfer to a surgical facility. (J Am Coll Cardiol 2004; 43:1943–50) © 2004 by the American College of Cardiology Foundation

The superiority of primary angioplasty (PA) over fibrinolytic therapy for the treatment of acute myocardial infarction (AMI) in lytic-eligible patients has been firmly established (1,2). Compared with fibrinolytic therapy, PA has been

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demonstrated to reduce the rates of death, stroke, recurrent ischemia, and re-infarction.

Certain clinical features of fibrinolytic therapy have been associated with very high morbidity and mortality. Among these are advanced age, anterior infarction, elevated heart rate, lower blood pressure, or higher Killip classes. Therefore, many physicians have selected a more aggressive approach for the management of patients with high-risk clinical features. Some physicians opt to transfer such patients to an interventional center, with or without previous administration of fibrinolytic therapy, despite the attendant risk and delay of transfer, which prolongs times to reperfusion (3) and thus could increase mortality (4). However, a recent meta-analysis of six trials of transfer for PA versus local thrombolysis demonstrated the superiority of PA, even in patients requiring transfer to an angioplasty center (5).

The frequent need to transfer high-risk patients early in the course of AMI underscores the need to extend the

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Abbreviations and Acronyms

AMI	= acute myocardial infarction
EC	= emergency center
ECG	= electrocardiographic
No SOS	= No cardiac Surgery On-Site study
NRMI	= National Registry of Myocardial Infarction
PA	= primary angioplasty
PAMI	= Primary Angioplasty in Myocardial Infarction trial
PCI	= percutaneous coronary intervention
TIMI	= Thrombolysis In Myocardial Infarction

availability of PA to more hospitals. One limitation of PA is the often-accepted requirement for on-site cardiac surgery. Only 39% of hospitals in the National Registry of Myocardial Infarction (NRMI) provide cardiac surgery (6). Most patients with AMI present to community hospitals without surgical programs, yet approximately 1,000 of these hospitals have diagnostic cardiac catheterization laboratories (7). It is not unusual for these diagnostic laboratories to be staffed by experienced interventionalists who routinely perform intervention at surgical centers.

An emerging practice in some U.S. hospitals that have catheterization laboratories but not cardiac surgery is to perform PA on-site as the routine first-line treatment for AMI. The success of these programs is multifactorial, based on having experienced interventionalists who routinely perform elective angioplasty at tertiary centers, an experienced staff, a well-equipped laboratory, and established protocols and agreements for emergent transfer to surgical centers (8).

Thus, hospitals with catheterization laboratories without in-house cardiac surgery have another option in the treatment of high-risk patients with AMI beyond administration of fibrinolytics or immediate transfer to a tertiary center: these hospitals could invest the effort and resources to develop PA programs locally. If such programs were found safe and effective, it could be clinically (and economically) advantageous to treat AMI patients on-site.

Several PA registries from hospitals without on-site cardiac surgery have reported excellent outcomes, which were not compromised by a lack of surgical facilities (8–13). Most of these are single-center registries that reported their own outcomes.

Multicenter studies of PA at hospitals without cardiac surgery are needed to help assess the feasibility, safety, and efficacy of this approach on a large scale. Accordingly, we designed the No Surgery On-Site (No SOS) registry arm of the randomized Air Primary Angioplasty in Myocardial Infarction (Air PAMI) study (14) to address this issue. We hypothesized that high-risk fibrinolytic-eligible patients treated on-site with PA will show clinical outcomes similar to those of the group that was transferred (Air PAMI transfer arm) for acute intervention, and that reperfusion will occur more quickly.

METHODS

Patient selection. Patients were considered if they had a clinical diagnosis of AMI: clinical symptoms lasting over 30 min and <12 h with electrocardiographic (ECG) evidence of ST-segment elevation or new left bundle branch block. To be included, patients were required to be fibrinolytic-eligible (except that age was not used as a qualification) and to have at least one high-risk qualifier: age over 70 years (no upper age limit), anterior MI, ECG demonstrating left bundle branch block, heart rate over 100 beats/min, systolic blood pressure <100 mm Hg in the absence of volume depletion, or Killip class 2 or 3 congestive heart failure (including the presence of rales, S_3 gallop, or pulmonary edema).

Patients were excluded from study participation if they were ineligible for fibrinolytic therapy (history of stroke or transient cerebral event in the last 6 months, major surgery or active gastrointestinal bleeding within the previous 2 months, organ biopsy within 2 weeks, cardiopulmonary resuscitation lasting ≥10 min or resulting in rib fracture, blood pressure >200 mm Hg systolic or 110 mm Hg diastolic), had cardiogenic shock (defined as systolic blood pressure ≤80 mm Hg in the absence of bradycardia or requiring vasopressors), or had a life-expectancy of <1 year. The study was conducted according to the principles of the Declaration of Helsinki, and all patients gave written, informed consent.

Eligible Air PAMI high-risk patients were randomized to receive either emergent transfer for PA or on-site fibrinolytic therapy. Eligible high-risk patients who presented to No SOS sites were prospectively enrolled in the registry arm of the study. The protocol recommended low-flow nasal oxygen, nitroglycerin, 325 mg oral aspirin, and intravenous beta-blockers. Anti-arrhythmics and calcium blockers were not routinely administered. Heparin was given according to the treatment arm to which the patient was assigned.

PA procedure. As soon as possible after enrollment, a bolus of intravenous heparin was administered, but a continuous infusion was not recommended. Patients were taken to the cardiac catheterization laboratory. Coronary angiography and left ventriculography were performed using low-osmolar ionic contrast medium (ioxaglate, Mallinckrodt, St. Louis, Missouri). Coronary intervention was performed unless the following exclusions precluded angioplasty: infarct vessel stenosis ≤70%, infarct vessel supplying so little myocardium that the angioplasty risk outweighed the benefit, unprotected left main stenosis >60%, or disease requiring coronary artery bypass graft surgery. The goal of angioplasty was restoration of normal coronary flow with minimal residual stenosis. Stenting was encouraged for residual lesions >30% or the presence of a coronary dissection. An activated clotting time of >350 s was maintained (200 to 250 s if platelet glycoprotein IIb/IIIa inhibitors were

used), and administration of fibrinolytic agents was discouraged.

No SOS registry site selection. We required the following: experienced interventionalists who regularly do elective intervention at a surgical center, an experienced catheterization team on a 24-h, 7-day per week call schedule, a well-equipped catheterization laboratory with digital imaging equipment, a full array of interventional equipment, intra-aortic balloon pump capability, formalized written protocols to be in place for immediate transfer to a surgical center, and rigorous and ongoing quality assurance and outcomes monitoring. We further required PA to be performed routinely as the first-line treatment of choice around the clock by the investigator's group. Nineteen sites were selected for the No SOS registry. Forty-nine percent of the No SOS registry patients were enrolled at sites just starting up new PA programs conforming to these standards. Thirteen other sites participated in the randomized Air PAMI portion of the study.

Clinical end points. The primary end point of major adverse cardiovascular events was the combined occurrence of death, non-fatal re-infarction, or disabling stroke by 30 days. Re-infarction was defined as recurrent ischemic symptoms in association with re-elevation of creatine phosphokinase to three times the upper limit of normal. Disabling stroke was defined as neurologic deficits significantly affecting activities of daily life. Ischemia was defined as persistent ischemic chest pain after reperfusion therapy or recurrent symptoms with ST-segment changes, new heart failure, murmur, or creatine phosphokinase re-elevation.

Data collection. Clinical data were collected and detailed case-report forms completed at each hospital by a designated clinical research coordinator. Physician investigators and coordinators were all volunteers; there was no compensation through research or industry grants or contracts. Case-report forms were sent to the PAMI Coordinating Center at William Beaumont Hospital for data entry and analysis. The core laboratory at William Beaumont Hospital reviewed all cineangiograms. One-month, six-month, and one-year follow-up data were obtained by telephone contact.

Monitoring of the case-report forms and hospital records was performed by the PAMI Coordinating Center. All primary end points, as well as a random sampling of 20% of patients, were reviewed by the clinical events committee, which was blinded to the treatment received.

Statistical analyses. Categorical variables, including end points of death, re-infarction, disabling stroke, and the combined primary end point of major adverse cardiovascular events, were examined using the chi-square test, as appropriate (expected frequencies >5); otherwise, the Fisher exact test was used. Continuous variables were examined using the Wilcoxon rank-sum test, because some of the variables were not normally distributed. The primary end point of this study was death, re-infarction, or disabling stroke by 30 days. A step-down logistic regression analysis was completed for one-year mortality, including independent variables with a value $p < 0.15$. A history of MI, diabetes, time to treatment, and randomization to transfer were included regardless of the p value. All analyses were completed using SAS version 8.0 (SAS Institute, Cary, North Carolina).

Table 1. Baseline Characteristics of the Air PAMI-No SOS Population

Variables	Transfer for PA (n = 71)	On-Site PA (n = 499)	p Value
Age (yrs)	62 ± 12	64 ± 12	0.50
Gender (%male)	76	71	0.35
Hypertension (%)	51	51	0.99
History of peripheral vascular disease (%)	10	10	0.99
Previous MI (%)	13	15	0.58
Previous CABG (%)	3	6	0.57
Diabetes (%)	23	19	0.51
High-risk qualifiers (%)			
Age >70 yrs	27	36	0.14
Heart rate >100 beats/min	37	34	0.66
SBP <100 mm Hg	38	44	0.31
Killip class >1	35	28	0.21
Anterior MI	77	52	<0.0001
LBBB on ECG	4	3	0.46
Two or more qualifiers	63	60	0.66
Three or more qualifiers	34	25	0.10

Data are presented as the median value ± SD or percentage of patients.

AMI = acute myocardial infarction; CABG = coronary artery bypass grafting; ECG = electrocardiogram; LBBB = left bundle branch block; MI = myocardial infarction; No SOS = No cardiac Surgery On-Site study; PA = primary angioplasty; PAMI = Primary Angioplasty in Myocardial Infarction trial; SBP = systolic blood pressure.

RESULTS

Demographic variables and high-risk characteristics. High-risk AMI patients were enrolled from August 1996 to March 1999. During this time period, 71 patients in the Air PAMI study were randomized to transfer for PA, whereas 500 patients were enrolled in the No SOS registry from August 1996 to June 1998. The demographic characteristics and high-risk enrollment criteria of the transfer and registry groups are outlined in Table 1. Anterior MI was more common in transfer compared with registry patients (77% vs. 52%; $p < 0.0001$).

Times to reperfusion in patients receiving on-site PA. For on-site PA, the median time from chest pain onset to emergency center (EC) arrival was 87 min; from EC arrival to first angiogram, 81 min; and from EC arrival to first balloon inflation, 105 min. The median time from pain onset to reperfusion was 201 min (Table 2).

Treatments and time delays in transfer patients. All of the 71 patients randomized to transfer were transferred (79% by ambulance and 21% by helicopter). No patient died or required cardiopulmonary resuscitation during transfer. Minor events during transfer were observed in only three patients (two patients with hypotension and one with confusion).

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Table 2. Time to Treatment in the Air PAMI-No SOS Study

Time Intervals (min)	Transfer for PA		On-Site PA		p Value
	Median (25th, 75th)	Mean ± SD	Median (25th, 75th)	Mean ± SD	
Chest pain onset to emergency center arrival	90 (45, 170)	140 ± 146	87 (45, 167)	146 ± 162	0.77
Emergency center arrival to angiography	155 (119, 194)	174 ± 81	81 (60, 115)	107 ± 127	<0.0001
Emergency center arrival to balloon inflation	166 (131, 240)	187 ± 75	105 (80, 139)	120 ± 69	<0.0001
Chest pain onset to reperfusion (balloon inflation)	270 (202, 362)	311 ± 146	201 (148, 326)	261 ± 171	0.017

Abbreviations as in Table 1.

Patients transferred for PA had longer median and mean times to treatment from first EC arrival to first balloon inflation (mean 187 vs. 120 min, $p < 0.0001$; median 166 vs. 105 min, $p < 0.0001$), which was due to the time involved in their transfer and starting the invasive procedure (Table 2). Thus, there was a mean delay in treatment of 67 min for the transfer group.

Treatments received. Among the transfer group, 100% underwent catheterization and 87% had PA; and among the on-site PA group, 100% underwent catheterization and 88% had PA (Table 3). Eight patients randomized to transfer did not receive PA; two patients were treated medically and six patients were referred for bypass surgery. Angiotensin-converting enzyme inhibitors were used more frequently in the transfer group (68% vs. 54%, $p = 0.034$). However, beta-blockers, abciximab, and stents were used more frequently in the on-site PA group (81% vs. 51%, $p < 0.0001$; 41% vs. 20%, $p = 0.0005$; and 53% vs. 34%, $p = 0.003$, respectively).

Multivessel disease and ejection fraction were similar between the groups (Table 4). However, angiographic data indicate improved outcomes for on-site PA (final Thrombolysis In Myocardial Infarction (TIMI) flow grade 3: 96% vs. 86%, $p = 0.004$; final stenosis: 9% vs. 18%, $p = 0.001$).

Complications. Table 5 lists the incidence of in-hospital complications. In the on-site PA group, only two patients (0.4%) were transferred for surgery due to failed PA; another 5% were transferred for emergency surgery because of critical coronary anatomy discovered on the triage angiogram. Of the transfer group, 5.6% underwent emergency surgery; none of these were transferred for failed PA. Twelve percent of the on-site PA group and 8% of the transfer group experienced bleeding requiring transfusion. There were no significant differences in complications between the groups.

Table 3. Treatments Received in the Air PAMI-No SOS Study

	Transfer for PA	On-Site PA	p Value
IV lytics	1 (1.4%)	28 (5.6%)	0.24
Catheterization	71 (100%)	499 (100%)	1.00
Revascularization	68 (96%)	473 (95%)	1.00
PA	62 (87%)	440 (88%)	0.89
CABG	10 (14%)	51 (10%)	0.32
Aspirin	68 (96%)	484 (97%)	0.46
ACE inhibitors	48 (68%)	270 (54%)	0.034
Beta-blockers	36 (51%)	405 (81%)	<0.0001
Digoxin	9 (12.7%)	83 (16.7%)	0.39
Abciximab	14 (20%)	205 (41%)	0.0005
Stent(s)	24 (34%)	263 (53%)	0.0029

Data presented are number (%) of patients.
ACE = angiotensin-converting enzyme; IV = intravenous; other abbreviations as in Table 1.

Clinical outcomes. On-site PA patients had a shorter length of hospital stay (5.2 ± 4.0 days vs. 6.1 ± 4.3 days, $p = 0.10$) (Fig. 1). At 30 days, 8.5% of patients randomized to transfer reached the primary end point of death, nonfatal re-infarction, or disabling stroke, as compared with 5.0% in the on-site PA group, (38% reduction, $p = 0.27$). There were no significant differences in 30-day outcomes between the groups, although there was a strong trend toward lower 30-day mortality in the on-site PA group (8.5% vs. 3.4%, $p = 0.054$).

Unadjusted mortality at one year was significantly higher for the transfer group versus on-site PA group (13% vs. 6%, $p = 0.043$), but after adjustment for differences in baseline variables, this difference was not significant. There were no significant differences at one year for the remaining outcomes (re-infarction: 3% vs. 2.6%, $p = 0.67$; disabling stroke: 0% vs. 2%, $p = 0.61$; and combined end point: 14% vs. 9%, $p = 0.19$) for the transfer versus on-site PA group.

A step-down multivariate logistic regression indicates that heart rate >100 beats/min, hypertension, chronic obstructive pulmonary disease, Killip class >1, no stent, and initial thrombus are significant predictors of mortality at one year (Table 6). Randomization to transfer for PA was not a predictor of mortality ($p = 0.86$).

DISCUSSION

Primary angioplasty is superior to fibrinolytic therapy for the treatment of patients with AMI and is potentially applicable to a much broader spectrum of patients with AMI. Only one in three patients with AMI is eligible to receive fibrinolytics, and only one in four actually receives it (15). Patients in whom fibrinolytic therapy is inappropriate have better outcomes with PA (16–18). Yet in 1999, only 16% of patients with ST-segment elevation AMI in the NRMI-3

Table 4. Angiographic Data

	Transfer for PA	On-Site PA	p Value
Multivessel disease	44 (62%)	280 (56%)	0.35
Ejection fraction	47 ± 12	48 ± 13	0.47
Ejection fraction <40%	28%	24%	0.52
Final			
TIMI flow grade 3	86%	96%	0.004
Percent stenosis	18 ± 22	9 ± 14	0.0012
Dissection	16%	9%	0.09
Thrombus	3.2%	4.1%	1.00
Initial			
TIMI flow grade 3	12.7%	13.8%	1.00
Percent stenosis	97 ± 8	97 ± 9	0.62
Dissection	13%	13%	0.86
Thrombus	67%	75%	0.19

Data are presented as the median value ± SD or number (%) of patients.
PA = primary angioplasty; TIMI = Thrombolysis In Myocardial Infarction.

database were treated with PA (19). This is partly due to the fact that most patients with AMI do not present to angioplasty centers.

There is a growing need to provide increased access to PA. Many recent trials have demonstrated the superiority of PA after transfer over on-site thrombolytic therapy for patients with AMI presenting to hospitals that do not provide percutaneous coronary intervention (PCI) (5,14,20,21). Because most patients with AMI present to community hospitals and most community hospitals neither can nor should be expected to provide on-site PA, systems are essential to ensure the rapid and routine transfer or prehospital ambulance triage of such patients to angioplasty centers capable of emergency intervention on a 24-h, 7-day per week basis.

The routine emergent transfer of patients with AMI, however, presents many difficulties (22). In the NRMI-2 and -3 registries, transfer for PA in the U.S. was associated with a median delay in time to reperfusion of 90 min, compared with on-site PA (195 vs. 105 min, $p < 0.001$) (3). In these registries, patients who were treated after 150 min had a 60% increase in mortality, compared with patients treated within 60 min ($p < 0.001$) (4). In view of the risk and delay of transfer, physicians at many community hospitals may be reluctant to transfer patients early in the throes of AMI, unless they deteriorate clinically, at which time the risk is much greater. Many patients may be too unstable on arrival to be considered for transfer. Many tertiary centers still do not offer PA as routine first-line care, even for their own patients with AMI, and thus may not have established protocols to perform immediate angioplasty on critically ill patients who they accept in transfer. Even if all PCI centers did provide PA as first-line therapy for AMI, the transfer of ever-increasing numbers of patients with AMI and high-risk acute coronary syndromes to tertiary centers could quickly overload their capacity. Thus, the transfer approach will ultimately necessitate and depend on the development of more interventional programs at more qualified community hospitals in broader geographic locations.

Table 5. In-Hospital Complications

Complication	Transfer for PA	On-Site PA	p Value
Asystole or heart block requiring pacemaker	2 (2.8%)	29 (5.8%)	0.41
Ventricular fibrillation (or tachycardia)	3 (4.2%)	25 (5%)	1.00
Pulmonary edema	7 (9.9%)	62 (12%)	0.54
Stroke or TIA	0	9 (1.8%)	0.61
Bypass surgery	10 (14%)	51 (10%)	0.32
Emergent bypass surgery	4 (5.6%)	27 (5.4%)	1.00
Emergent bypass surgery due to failed PA	0	2 (0.4%)	1.00
Bleeding requiring transfusion	6 (8%)	61 (12%)	0.35

Data are presented as the number (%) of patients. Patients might be included in more than one complication category.
PA = primary angioplasty; TIA = transient ischemic attack.

All of these considerations support the need to expand the availability of centers that are capable of offering PA around the clock. The need for more interventional facilities can be projected to increase even further in the near future, with the aging of the baby boomers and the increasing application of PCI to more patient groups. This increasing need for coronary intervention may well outstrip the waning need for cardiac surgery facilities. Uncoupling angioplasty from the requirement for on-site coronary bypass surgery will reduce the pressure to open more low-volume surgical programs to support needed new angioplasty programs (22).

The availability of qualified hospitals and operators who perform PA is limited in part by various local requirements for on-site cardiac surgery. For example, at least 11 states still have regulations prohibiting the use of PA at nonsurgical hospitals under any circumstances. Investigators from eight such states requested to participate in our registry but were not allowed to do so because of these regulations.

The newly revised American College of Cardiology/American Heart Association guidelines for PCI (23) now accept PA at hospitals without on-site cardiac surgical backup, for which there is a "class IIb" indication (usefulness/efficacy less well established by evidence/opinion), provided that at least 36 PA procedures per year are performed at such hospitals, the interventionalist performs at least 75 procedures per year, procedures are performed within 90 ± 30 min of arrival, and there is a proven plan for rapid access to a cardiac surgical center. These guidelines also include tables listing further operator, institutional, and patient selection criteria for the performance of angioplasty and emergency coronary bypass surgery at such hospitals, as originally proposed by Wharton et al. (8).

There are over 800 community hospitals in the U.S. with cardiac catheterization laboratories that do not have cardiac surgery (7), many of which are staffed by experienced interventionalists. In view of the potential advantages of PA and the need to extend its availability to more patients in broader geographic locations, the question of whether PA in

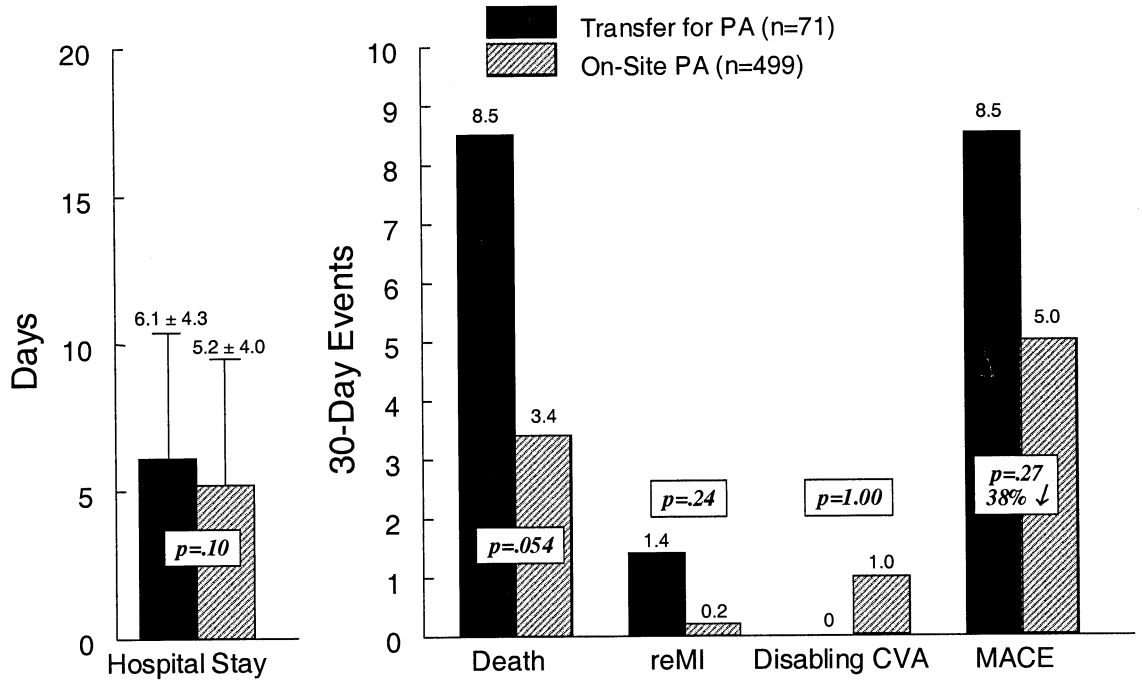

Figure 1. Comparison of lengths of stay and 30-day outcomes between patients transferred for primary angioplasty (PA) to tertiary cardiac surgical centers and those treated with on-site PA at hospitals without cardiac surgery. The graph on the **left** demonstrates a trend toward a shorter hospital stay in patients treated with on-site PA. The graph on the **right** demonstrates a strong trend toward lower mortality at 30 days in patients treated with on-site PA, but no significant differences in recurrent myocardial infarction (reMI), disabling cerebrovascular accident (CVA), or the combination of these major adverse cardiovascular events (MACE) at 30 days. **Solid bars** = patients transferred to tertiary centers for PA; **striped bars** = patients treated with on-site PA at nonsurgical hospitals.

the treatment of AMI can be performed safely and effectively in primary care hospitals must be addressed.

The efficacy and safety of PA versus fibrinolytic therapy at hospitals with off-site surgical backup was recently demonstrated in the randomized Cardiovascular Patient Outcomes Research Team (C-PORT) trial (24). This 453-patient study demonstrated the superiority of PA in reducing the composite end point of death, recurrent AMI, and stroke at six weeks and six months, compared with fibrinolytic therapy at hospitals without cardiac surgery. The median length of stay was also reduced in the PA group. This trial did not compare on-site PA at nonsurgical hospitals with transfer to tertiary cardiac surgical centers for PA.

A recent report from the NRMI investigators regarding in-hospital mortality and times to reperfusion for PA in patients with ST-segment elevation AMI or left bundle branch block lends further support for PA at hospitals without on-site cardiac surgery (25). Of 30,538 patients treated with PA, 1,935 of these procedures were performed at 97 hospitals without on-site cardiac surgery (of which 50 also provide nonemergent angioplasty), with comparable in-hospital mortality and shorter times to reperfusion for nontransfer patients. The authors concluded that this prompt treatment at nonsurgical hospitals, with no added risk, was an alternative to transfer to hospitals with on-site cardiac surgery and may have implications for national public health.

Table 6. Multivariate Predictors of Mortality at One Year in the Air PAMI-No SOS Study

Variables	Odds Ratio	95% CI	p Value
Heart rate >100 beats/min	2.21	1.05–4.62	0.036
History of hypertension	2.91	1.29–6.60	0.010
History of COPD	3.62	1.07–12.2	0.038
Killip class >1	3.43	1.64–7.15	0.001
No stent	2.59	1.17–5.72	0.019
Initial thrombus	4.90	1.41–17.0	0.012
Randomized to transfer	1.10	0.37–3.31	0.86

CI = confidence interval; COPD = chronic obstructive pulmonary disease; other abbreviations as in Table 1.

The present study. This series represents the largest prospective multicenter experience of PA in hospitals without on-site cardiac surgery. Most previous reports of PA at nonsurgical hospitals represent the experiences of single centers reporting their own outcomes (8,10–13). In this study, all clinical outcomes were collected and adjudicated by a single coordinating center, and all angiograms were submitted for core laboratory analysis. This study demonstrates that clinical outcomes in patients treated with PA at qualified hospitals with off-site cardiac surgical backup are similar to outcomes of patients transferred to tertiary surgical centers for PA, with more rapid reperfusion at the nonsurgical centers providing on-site PA.

Study limitations. One possible criticism of the on-site PA data is that there could have been a selection bias. However, all patients were enrolled prospectively if they met the

selection criteria. A screening log was kept on all incoming AMI patients to address a potential selection bias. The higher-than-expected incidence of anterior MI in the group randomized to transfer may have been because it was easier for the small primary care hospitals that were screening patients for Air PAMI to select obvious patients (anterior MI) for randomization. The No-SOS sites were performing primary PCI in all patients as routine first-line care, with less likelihood of a selection bias.

Another limitation is that the patients in this series were not randomized. Although our experience demonstrates outcomes that can be achieved at community hospitals without cardiac surgery, this finding provides no indication of whether alternative treatment with fibrinolytics or randomization to transfer to a surgical center versus on-site PA might have led to similar outcomes. However, pooled data from 23 randomized studies of PA versus fibrinolytics has already demonstrated the superiority of angioplasty (1). It would seem that further randomized studies are unnecessary to validate PA at centers without cardiac surgical programs if such centers can demonstrate outcomes equivalent to those reported in these studies. This registry has demonstrated such equivalence. In addition, randomization to on-site PA versus fibrinolytics or transfer will reduce procedural volumes at participating hospitals; thus, the randomization process itself might adversely influence outcomes by this dilutional effect on PA volumes.

The outcomes of our study may not be reproducible by other hospitals without cardiac surgical programs if they do not maintain the rigorous institutional, operator, laboratory, and procedural standards of this protocol, including ongoing analysis of outcomes and case review. The outcomes of PA are very much dependent on operator expertise and institutional commitment. We believe that cardiologists can achieve results similar to ours at institutions that establish programs adopting rigorous standards such as those we propose (see Methods, under No SOS Registry Site Selection heading).

The decreased use of stents in patients transferred to tertiary centers for PA, compared with the No SOS community hospitals, was unexpected. However, stenting has only been shown to reduce recurrent ischemia, but not death, re-infarction, or stroke (26,27), and thus the difference in stent use should not be expected to have influenced the combined primary end point of our study. Also, because stenting does not improve TIMI flow (26,27), the higher rate of TIMI flow grade 3 in the No SOS group, as adjudicated by the core laboratory, cannot be attributed to increased stent use.

Newer hospitals just beginning to offer PA raise particular concern that their inexperience may lead to suboptimal outcomes. However, 49% of our study patients were enrolled at sites just starting up new PA programs that could meet our standards. The outcomes of these sites were similar to those of hospitals with more established programs. The learning curves of these sites were not perceptible in their outcomes data.

Although we have demonstrated similar clinical outcomes between on-site PA and PA after transfer, as postulated, the volume of patients in our transfer group is small. A larger number of patients in this group may have allowed the trends we observed, favoring the on-site PA group to have achieved statistical significance.

The surprisingly rapid enrollment of patients for on-site PA in the No SOS registry, compared with the much slower enrollment in the Air PAMI study, suggests that on-site PA is likely to become the preferred approach at qualified hospitals without cardiac surgery.

Conclusions. When prospectively compared with similar patients transferred for PA, patients receiving on-site PA had more rapid reperfusion and similar 30-day outcomes. Primary angioplasty in patients with high-risk AMI at hospitals with off-site cardiac surgical backup is as safe and effective and significantly faster than PA after transfer to a surgical facility.

Community hospitals wishing to establish successful PA programs must adopt rigorous standards for operators, staffing, laboratories, equipment, and case selection and maintain ongoing outcomes analysis and case review. Participation in the American College of Cardiology's National Cardiovascular Data Registry should be strongly encouraged.

These results should not be understood to mean that PA can or should be done at every hospital with cardiac catheterization facilities. However, this report does suggest that the lack of cardiac surgery backup, per se, need not limit the safety or efficacy of the broader application of this optimal treatment for patients with AMI.

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APPENDIX

For a list of the PAMI-No SOS study Group Clinical Centers, Coordinating Center, and Core Angiographic Laboratory, please see the June 2, 2004, issue of *JACC* at www.cardiosource.com/jacc.html.